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Treatment of Humeral Nonunions with Cancellous Allograft, Demineralized Bone Matrix, and Plate Fixation

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Melvin Rosenwasser, MD Professor of Orthopaedic Surgery Department of Orthopaedic Surgery 622 West 168th Street, PH 11-1129 New York, NY 10032 (212) 305-3912 fax (212) 342-1749 mpr2@columbia.edu Abstract: Autologous iliac crest bone graft is routinely recommended in the treatment of humeral nonunions. Due to the risks inherent in autograft harvest, we evaluated 11 patients (mean age 62 years; 5 males and 6 females) with humeral nonunions who were treated with allograft, demineralized bone matrix, and plate fixation to determine their clinical outcome. The mean duration of the nonunion was 24 months (range, 4 – 120 months). At a mean follow-up of 33 months (range, 25 –42 months; minimum 2 years) 10 of the 11 nonunions (91%) had healed. One patient required a second operation to gain union. The nonunion that failed to heal eventually required a hemiarthroplasty, secondary to blade plate cut out of the humeral head. Patient outcomes were evaluated with the D.A.S.H. questionnaire demonstrating 4 excellent, 5 good, 2 fair, and no poor results at follow-up. All patients had functional shoulder and elbow motion. These results show that allograft and demineralized bone matrix can be a useful adjunct to plate fixation in the treatment of humeral nonunions.

Key words: humerus, nonunion, allograft, demineralized bone matrix

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Introduction

Humerus fracture nonunions are uncommon, with reported rates of between 1 and 15% in large series. ^{6,8,12,19} When treating a humerus nonunion, most authors recommend plate and screw fixation with autologous iliac crest bone grafting (ICBG), especially when the nonunion is considered atrophic. ^{2,6,7,10,12,18,21,24-30,33,34}

The goal of autologous bone graft from the iliac crest is to provide the nonounion site with osteoconductive, osteoinductive, and osteogenic factors to promote bone healing and to fill bone defects. ²² However, the risks of ICBG harvesting have been well documented and include infection, nerve injury, fracture, and most commonly pain (38%) of patients). 11 An alternative to autogenous bone graft is freeze-dried, irradiated, human cancellous bone allograft ("croutons") and demineralized bone matrix (DBM). The cancellous allograft (CA) provides a scaffold for osteoconduction, fills bone defects, and can be impacted. We have had excellent results using CA to supplement open reduction and external fixation in unstable distal radius fractures needing supplemental bone graft.¹⁴ DBM has proved to be highly osteoinductive and readily osteoconductive. ^{22,31,32} At our institution, CA and DBM (Grafton DBM-Osteotech) is provided by the Musculoskeletal Transplant Foundation (Edison, NJ). We routinely use 30-mL containers of CA (\$376) and 5-mL tubes of DBM gel (\$644). The allograft and DBM are readily available in the operating room and their use prevents donor site morbidity while decreasing anesthesia time for the patient. To our knowledge, no clinical data have been published regarding the use of CA and DBM in the treatment of humeral nonunions.

The purpose of our study was to retrospectively evaluate all patients with humeral nonunions who were treated with CA, DBM, and plate fixation by the senior author (M.P.R.) to determine their clinical outcome.

Materials and Methods

Between June 1998 and December 2001, 11 consecutive patients with humeral nonunions were treated with CA, DBM, and plate fixation by the senior author (M.P.R.). The nonunion was in the mid-shaft in 6 patients, distal-third in 3, and proximal-third in 2. The mean age of the patients was 62 years (range 25-77 years) with 5 males and 6 females. Preoperative and postoperative information is summarized in Table 1.

The original fracture was the result of a fall from a standing height in 6 patients, motor vehicle accident in 3, fall from a truck in 1, and assault ("mugging") in 1. One of the distal third nonunions occurred distal to the tip of a hemiarthroplasty after a fall down stairs. All of the nonunions were closed fractures and none had a history of infection. The left arm was involved in 9 patients and the right arm in 2. Three of the nonunions involved the dominant arm. The initial fracture treatment in six patients was operative: an intramedullary nail in 5 patients and a 3.5 dynamic compression (DC) plate in 1. Five patients were originally treated closed: a fracture brace in 3 patients, hanging cast in 1, and sling in 1.

Prior to presenting to our institution, 8 of the 11 patients had undergone a total of 14 operations in an attempt to gain union (average 1.3, range 0-4 previous operations). Four patients had had two or more operations. Three patients had failed one or more plate fixation attempts with iliac crest autograft after the original intramedullary nail had failed. The patient originally treated with a hanging arm cast had undergone two plate fixation attempts, one with and one without iliac crest autograft. Five patients had also failed electrical stimulation augmentation, one after a failed intramedullary nail and two after failed plate fixation with iliac crest autograft. At the time of our initial operative procedure, five patients had plates and two had intramedullary nails that were either loose or broken.

In each case, the indication for the operation was a painful, unstable nonunion in an unsatisfied patient. The mean duration of the nonunion from initial injury to our operation was 24 months (range, 4- 120 months). The only patient operated upon prior to 6 months of no union (our definition of nonunion) had early failure of plate and screw fixation and an unresolved radial nerve palsy 4 months after original injury. The nonunion healed successfully and the radial nerve palsy resolved after our operative procedure.

Nine of the nonunions were atrophic (nonvital) and two hypertrophic (vital) by preoperative radiograph evaluation and confirmed intraoperatively. ^{3,27} Both hypertrophic nonunions had been treated previously by one attempt at an intramedullary nail. Five nonunions were found to be synovial pseudarthroses intraoperatively, as evidenced by a synovial-lined, fluid-filled cavity at the nonunion site. ^{3,25}

Surgical Technique

Patients were placed in the lateral decubitus position or supine after a combined anesthetic technique of intrascalene block and general endotracheal anesthesia. The arm was thoroughly draped free to allow access to both the anterior and posterior aspects of the arm and shoulder. This allowed for both hardware removal of a nail or plate and any new approach for plate fixation. If hardware was in place, this was removed first through the old incisions if possible.

Eight nonunions (5 mid-shaft, 3 distal-third) were approached through a posterior approach (two through previous incisions). A midline longitudinal incision was made from the tip of the olecranon distally to the proximal third of the humerus. The interval between the long and lateral heads of the triceps was used and the radial nerve and companion vessels were identified proximally and protected with vessel loop retractors throughout the case.

The two proximal-third nonunions were approached through the deltopectoral interval, one through a previous incision, from the acromioclavicular joint proximally to the deltoid insertion distally. The axillary nerve was identified and protected in each case.

One mid-shaft nonunion was approached through the previous anterolateral incision which had been used on two previous occasions. The radial nerve was identified and protected at all times while the deltopectoral interval was developed proximally and the brachioradialis/brachialis interval distally.

After the initial approach, the fracture site was visualized and subperiosteal elevation was performed only to identify fracture fragments and retrieve any retained hardware. Muscular or vascular attachments to the fracture fragments and shaft were maintained and care taken not to devascularize the bone. All avascular scar and synovial tissues were debrided and removed. All nonunion sites had tissue and fluid sent for culture. If the humeral shaft ends were capped or sclerotic, the intramedullary canal was opened with curettes, gouges, or a drill in order to increase vascularity. The proximal and distal surfaces of the humerus were usually gouged and "rosetted" in order to increase surface area and bleeding for shaft and bone graft consolidation. ²⁷

In the 6 mid-shaft and 1 distal-third nonunions, a plate was then selected and contoured appropriate to the width and length of the humeral shaft. A 4.5 DC plate was used in 5 patients, a 4.5 LCDC plate in 1, and a 3.5 DC plate in 1. The average length of the plate was 10 holes (range, 7-14 holes). From a posterior approach, the plate was placed on the posterior or posterolateral aspect of the shaft and underneath the radial nerve as it crossed the humeral shaft. From the anterolateral approach, the plate was placed on the lateral aspect of the humeral shaft. At least three screws and six full cortices were affixed above and below the fracture site in all cases (range 6 to 10 cortices). Lag screws were used when possible and plates were applied in standard compression mode whenever possible. Schuhli washers or polymethylmethacrylate (PMMA) cement was used in screw holes whenever cortical screw purchase was inadequate and loosening anticipated. Schuhli washers were utilized in two plate holes in two patients and PMMA in two holes in one patient and one hole in another patient.

In four patients with osteopenic bone or bone loss due to previous operations, a nonvascularized fibular allograft was used to maintain humeral length and reinforce screw purchase. These patients had anywhere between 2 to 6 cm of bone loss at the nonunion site following surgical resection to viable bone. The fibular allograft was tapered and press-fitted into the intramedullary canals proximally and distally prior to plate application. The plate and screws were then applied across the construct with the screws achieving "quadricortical" fixation as described by Wright. ³³

In the patient with a nonunion distal to a previous hemiarthroplasty, a 3.5 reconstruction plate was applied to the lateral distal humerus and used in conjunction with the intramedullary fibular allograft to obtain stable fixation. Due to the spiral nature of the nonunion, this construct allowed "tricortical" fixation distally in some areas and "quadricortical" fixation in other areas. However, proximally there were areas of only unicortical fixation due to the prosthesis and three cerclage wires were applied to compress the plate to the shaft. In the end, this construct was stable to intraoperative flexion and rotation of the humerus.

The two proximal-third nonunions were treated with 4.5 AO blade plates. Both were 6 hole plates with 30mm blades. In order to provide additional bone stock proximally in one patient, a humeral cortical allograft strut was placed into the humeral head proximally and into the medullary canal distally resulting in "quadricortical" fixation in some areas.

One distal-third nonunion was treated with two reconstruction plates. A 4.5 reconstruction plate was placed posterolaterally and a 3.5 reconstruction plate was

contoured around the medial epicondyle to obtain 90-90 fixation. The ulnar nerve was protected and transposed anteriorly.

After all internal fixation was secured in all eleven patients, 30-mL cancellous bone allograft (CA) and 5-mL of demineralized bone matrix (DBM) gel was applied to fill any bone defects and placed circumferentially around the nonunion site and along the medial and lateral gutters of the humeral shaft to promote bone healing.

Postoperatively, ten patients had their arms maintained in a sling for 10-14 days with passive motion allowed at the shoulder and elbow. Five patients were also fitted with a fracture brace in addition to their sling. Once the wound was healed and initial pain subsided, the sling was discontinued and formal physical therapy begun with full active motion allowed at the shoulder and elbow. The fracture brace was discontinued when the humerus was pain-free and healed by xray.

One patient was placed in a shoulder spica cast postoperatively. This was the patient with the nonunion distal to the tip of a humeral prosthesis. Although the final plate and allograft construct described above was stable in the operating room, the spica cast was placed because the bone was extremely osteopenic, only a single 3.5 reconstruction plate was able to be utilized, and the humeral prosthesis prevented bicortical screw purchase proximally. The spica was maintained for 10 weeks until radiographic and clinical healing was evident.

Patient Evaluation

All patients were evaluated preoperatively, postoperatively, and at follow-up by the senior author (M.P.R.). A standard physical examination of the upper extremity and radiographs of the humerus were performed. Osseous union at follow-up was defined radiographically as bridging trabecular bone across the previous nonunion and clinically by the absence of pain and motion with manual stressing of the nonunion site. The humeral head and entire shaft had to move as a unit to be considered healed.

At the most recent follow-up visit, patients completed the Disabilities of the Arm, Shoulder, and Hand Questionnaire (DASH) to evaluate patient outcome. ¹⁵ The DASH score ranges from 0 to 100 with a higher score indicating more severe disability. Since this study was retrospective, neither the DASH nor any other shoulder-specific score was available preoperatively.

Results

At a mean follow-up of 33 months (range, 25-42 months; minimum 2 years) 10 of the 11 nonunions (91%) had healed. Nine of the 11 nonunions healed after the index operation, giving an initial healing rate of 82%, as one patient required a second operation to gain union. The average time to union was 12 weeks (range 9-28 weeks) after the index operation with CA, DBM, and plate fixation.

Patient outcomes as evaluated with the DASH questionnaire demonstrated 4 excellent, 5 good, 2 fair, and no poor results at follow-up. Active motion of the shoulder and elbow joints was measured with the patient in a sitting position. Average forward

elevation at latest follow-up was 160 degrees (range 130-170 degrees). Average external rotation was 34 degrees (range 30-45 degrees). Average elbow arc of motion was 5-135 degrees (range 0-140 degrees).

The nonunion that failed to heal was atrophic, proximal and eventually required a hemiarthroplasty. This patient had undergone 4 previous operations including two antegrade intramedullary nailings, an open bone grafting with the nail in place, and an open reduction internal fixation with figure of eight wires and iliac crest bone graft. Our first fixation attempt was with a 6 hole AO blade plate with a 30mm blade, a humeral allograft strut, CA, and DBM. The blade cut out of the humeral head within 2 weeks but the humeral and glenoid articular surfaces were intact. Our second fixation attempt was with an 8 hole AO blade plate with a 40mm blade. The previous humeral allograft was left in place and supplemented with Norian bone cement to fill the humeral head defect. Cancellous allograft and DBM were again used as supplementary bone graft. This construct remained in place for 6 months until the blade again cut out of the humeral head as the head subluxed anterior and inferior. Due to erosion of the humeral head and glenoid cartilage, the patient was then definitively treated with a proximal humerus hemiarthroplasty. At 36 months follow-up, the patient had functional shoulder range of motion and a DASH score of 38 (Good result).

The patient who required a second operation to gain union had undergone a previous retrograde intramedullary nail for a midshaft fracture, followed by bracing and electrical stimulation after the fracture went on to nonunion. Initially the nonunion was considered hypertrophic. Our first fixation attempt was with a 7 hole 4.5 LCDC plate with 3 screws and 6 cortices of purchase obtained proximal and distal to the nonunion

site, along with the addition of CA and DBM. Against our recommendations, the patient was lifting a heavy object approximately 11 weeks postoperatively and noted pain.

Subsequent xrays revealed screw pullout at several locations and angulation of the bone at the nonunion site. The patient had also been using steroid creams for the treatment of psoriatic dermatitis although they had been advised not to use any steroid based creams. The patient was then treated with a 12 hole 6.5 DC plate with 5 screws and 10 cortices of purchase obtained proximal and distal to the nonunion site. An intramedullary fibular allograft was also utilized to enhance screw purchase in the osteoporotic bone and CA and DBM were again added as additional bone graft. Since this was only the third patient to have allograft and DBM as their sole supplementary bone graft, an iliac crest aspiration of cells was added to the nonunion site to aid in osteogenesis. The nonunion healed 12 weeks after the second operation and at follow-up the patient had a DASH score of 24 (Good result).

Other than the two patients above, no other complications occurred. There were no superficial or deep wound infections. Two patients who had preoperative radial nerve palsies had full recovery of the radial nerve by 6 months postoperatively.

Discussion

Our results show that humeral nonunions can be successfully treated with plate fixation supplemented by cancellous allograft (CA) and demineralized bone matrix (DBM). The rate of union was comparable to past studies utilizing ICBG.

1,2,6,7,9,10,12,13,16,20,21,25-30,33,34 Nine of the eleven nonunions were atrophic and seven of these healed after the first operation. Of the two hypertrophic nonunions, one healed

after the index operation and the other required a second operation with added stability to gain union. In all patients, ICBG site complications were avoided and anesthesia time was reduced. The cost of one hour of operating time at our institution is approximately \$2,900. If an ICBG operation takes 30 minutes as a separate procedure, the cost savings of using CA and DBM is approximately \$430 (\$1,450 OR time - \$1,020 DBM/CA cost).

Our clinical outcomes were also similar to past studies utilizing internal fixation and ICBG. ^{25,26} Although we did not have preoperative DASH scores, our postoperative DASH scores (average 26) were comparable to other studies. ^{25,26} In 1999 Ring evaluated 17 humeral diaphysis nonunion patients with a preoperative DASH of 77 (range 53-91) that improved to 24 (range 1-78) postoperatively. ²⁶ In 2001 Ring studied 25 proximal humerus nonunion patients with a preoperative DASH of 77 (range 53-94) that improved to 21 (range 1-53) postoperatively. ²⁵ Our patients probably would have had a similar preoperative DASH scores given that they all complained of significant preoperative pain and disability.

Many authors have used iliac crest autograft (ICBG) in addition to internal fixation for humeral nonunions with union rates ranging from 76 to 100%. 1,2,6,7,9,10,12,13,16,20,21,25-30,33,34 Some authors use ICBG in all patients. 2,6,10,12,16,20,25,26,28-30,33,34 Other authors recommend ICBG only when the nonunion is atrophic. 1,7,13,21,23,27 However, several authors have specifically noted complications related to the ICBG site. 17,24,25,28,33,34 In 2002, Rubel had one case of infection of the ICBG site in 37 patients. 28 In 2001, Ring noted 2 complications in 25 patients, one iliac wing fracture and one patient requiring a blood transfusion after graft was obtained from both posterior iliac crests. 25 In a 1997 series of 19 patients, Wright had one patient with

persistent iliac crest pain at 19 months follow-up. ³³ In 1995, Jupiter reported a herniation through the iliac crest defect after harvest. ¹⁷ In a 1993 series of 9 patients, Wright had one patient with an ICBG site infection that resolved with antibiotics. ³⁴

We believe that neither of our complications could be directly attributed to bone graft failure or lack of osteogenic potential. Both complications occurred in proximal third nonunions which are notorious for their difficulty of fixation. 9,23,25 The patient who eventually required a hemiarthroplasty failed mainly because of poor bone stock in the humeral head and neck. Even a bulk allograft, norian bone cement, and a longer blade and blade plate could not overcome the proximal bone deficit. It is doubtful the addition of ICBG would have resulted in success given the patient had failed four previous operations that twice included ICBG, although rigid fixation was not utilized previously. The patient who required a second operation to gain union failed because of poor patient compliance and a plate that was too short (7 holes, six cortices proximal and distal) and too small (4.5 LCDC). Once a longer (12 holes, 10 cortices proximal and distal) and larger (6.5 DC) plate was placed with CA, DBM, and iliac crest aspirate the humerus healed. The only reason iliac crest aspirate was utilized the second time was that this was our first failure with CA and DBM. However, we have shown in seven subsequent nonunions that the humerus will heal with the addition of only CA and DBM and that no iliac crest aspirate is required. Although a minimum of 6 cortices proximal and distal to the nonunion have been recommended in the past by Healy, we believe the use of only 6 cortices contributed to our failure and we now routinely use 8 to 10 cortices proximal and distal to the nonunion site. 12

There have been a few reports of the use of CA or fibular allograft alone in the treatment of humeral nonunions. ^{4,5,9} In 2004, Galatz treated four of thirteen surgical neck nonunions with a blade plate and CA. ⁹ The other nine nonunions were treated with ICBG. All thirteen nonunions healed. The authors main indication for using CA over ICBG was to minimize morbidity in patients over 70 years old. In 1994 and 2000, Crosby and Dao treated 12 humeral shaft nonunions with compression plating and fibular allograft as the only bone graft material resulting in an 83% union rate. ^{4,5} The two failures were in elderly, debilitated patients with multiple medical problems including alcoholism and a history of falls postoperatively.

As Wright and Crosby have reported, we also had success using a structural fibular allograft and quadricortical fixation in patients with osteopenic bone or bone loss.

4,33,34 All these patients had had at least one previous operation. We also successfully used Shuhli washers and PMMA cement whenever single screws were not firmly fixed in osteopenic bone.

This study had the limitation of being retrospective and not having a comparable group treated with ICBG and plate fixation. A future randomized, multi-centered study could be designed to compare ICBG to DBM and CA in the treatment of properly indicated humeral nonunions. It must be emphasized that none of our patients had a history of infection or open fracture and this affected our bone graft indications. Severely atrophic or nonviable nonunions should always be considered for ICBG with or without vascularized bone grafting. The patient's overall medical status, age, and ability to withstand added morbidity should also be considered when selecting bone graft. In the

appropriate indications, plate fixation supplemented with CA and DBM can result in a reliable rate of healing and outcomes in humeral nonunions.

Figure Legends

<u>Figure 1ab</u>. Anteriorposterior (AP) and lateral radiographs of the humerus 10 months after IM nailing. The nonunion is unstable and atrophic.

<u>Figure 1cd</u>. Healed nonunion 39 months after plate fixation supplemented with cancellous allograft and DBM.

<u>Figure 2ab</u>. Anteriorposterior radiographs of the proximal humerus initially and 18 months after closed treatment. The nonunion is unstable and shows no signs of healing.

<u>Figure 2cd</u>. Healed nonunion 31 months after blade fixation supplemented with cancellous allograft and DBM.

Tables

Table 1. Pre and Post Operative Patient Data

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